

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION)	<u>REDACTED PUBLIC VERSION</u>
and BOSTON SCIENTIFIC SCIMED, INC.,)	
)	
Plaintiffs,)	
)	C.A. No. 18-1869-CFC-CJB
v.)	
)	
MICRO-TECH ENDOSCOPY USA INC.,)	
MICRO-TECH (NANJING) CO., LTD., and)	
HENRY SCHEIN INC.,)	
)	
Defendants.)	

**LETTER TO THE HONORABLE CHRISTOPHER J. BURKE
FROM ANDREW C. MAYO**

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Dear Judge Burke:

Plaintiffs' expert Karl Leinsing has provided 3 reports in this action: (1) an Opening Report on infringement of the 3 patents in suit (Ex. A); (2) a Rebuttal Report on validity of those patents (Ex. B); and (3) a Reply Report on infringement (Ex. C). Pursuant to Section 10 of the Scheduling Order, Defendants request that the Court strike *new* arguments in each of three expert reports that are inconsistent with positions disclosed by Plaintiffs in discovery, as described further below. As shown in Exhibit D, Defendants identified that Mr. Leinsing's Rebuttal Invalidity Report alone provided over 50 new arguments – many of which he abandoned during his deposition – regarding anticipation and obviousness. Because Mr. Leinsing has either abandoned or admitted that many of his new arguments are contrary to the Federal Circuit's ruling that claim 1 of the '371 patent is invalid, Defendants' Motion is focused on the 5 sets of new arguments identified below. Striking those arguments will streamline summary judgment proceedings and allow the Court to focus on an appropriate set of dispositive issues.

Governing Legal Standards

The instant motion is governed by the *Pennypack* factors for striking untimely disclosure. *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904-05 (3d Cir. 1977); accord, e.g., *Integra Lifesciences Corp. v. Hyperbranch Med. Tech. Inc.*, Civil Action No. 15-819-LPS-CJB (D. Del. March 28, 2018) (pattern of changing positions supports striking late disclosed theories in expert reports); *TQ Delta, LLC v. Adtran, Inc.*, 2020 WL 4529865, *1–*2 (D. Del. 2020) (courts are more willing to strike new theories in complex litigation, even if *Pennypack* factors arguably are not met). The particular reluctance of the Court to permit plaintiffs in patent infringement cases to rely on late-disclosed theories is mandated by fundamental fairness: “[i]f Plaintiffs had timely disclosed this infringement theory, Defendant may have been able to assert different theories of non-infringement and invalidity.” See *HSM Portfolio LLC v. Elpida Memory Inc.*, Civil Action No. 11-770-RGA, at *5-6 (D. Del. Feb. 11, 2016) (striking portions of Plaintiffs' expert infringement report). The Court in *HSM* recognized that, even though Defendant had filed a supplemental report responding to Plaintiffs' new theories, that did “not overcome the prejudice experienced by Defendant” due to the delay in Plaintiffs' disclosure. *Id.*

In this case, expert discovery closes in two days, and the deadline for filing summary judgment motions is in less than three weeks. Plaintiffs nonetheless have changed infringement theories multiple times, including on the “bushing” and “clip assembly” claim terms, and by those untimely changes have attempted to alter the entire landscape of the infringement and invalidity issues for trial. Those changes would render meaningless much of the discovery that has been conducted based on Plaintiffs' positions in its Infringement Contentions. To permit these changed theories at this late stage of the case would require the Court to abandon the current trial date and postpone summary judgment briefing, thus disrupting the entire schedule. Moreover, Plaintiffs new alleged priority date for the '245 patent and 50 plus new disputed terms in the Leinsing Reports do not appear to have been disclosed in good faith – indeed, as noted below, Plaintiffs have reneged on an affirmative agreement with Defendants and waited until rebuttal reports to surface dozens of new issues on prior art references. As a result, and as explained further below, all five *Pennypack* factors (prejudice, no reasonable possibility to cure, disruption to the trial, lack of good faith, and importance of the withheld information) are present here, which squarely supports Defendants' request that the Court strike the new and untimely theories.

The Court Should Strike Leinsing's Untimely Opinions

1. New Infringement Arguments on the “bushing” for the '371 and '725 Patents

Mr. Leinsing departs from Plaintiffs' previous infringement position on the claimed “bushing” in two ways, each of which independently supports striking Mr. Leinsing's Report regarding claim element 1[d] of the '371 patent and claims 2 and 3 of the '725 patent. As Judge Andrews has recently stated “Opening expert reports are not the appropriate time to disclose new infringement allegations.” *TQ Delta v. Amtran*, Civil Action No. No. 14-954-RGA, 2019 WL 4346530 at *2 (D. Del. Sep. 12, 2019) (striking new infringement theory not disclosed in infringement contentions).

a. '371 Patent Claim Element 1[d] – “tab on the distal end of the bushing”

In their Final Infringement Contentions, Plaintiffs labeled the “reduced diameter portion” of the bushing as the “tab” of Claim 1, Element d. Ex. E at 5. Mr. Leinsing copied and pasted Plaintiffs' Final Contentions into his Opening Infringement Report, but he then modified those contentions as shown below in the following redline comparison.

Each Accused Original/Buckle Device further includes a three-pronged spring tab, with each prong of the three-pronged spring tab configured to protrude out of an opening along the circumference of the ~~reduced diameter distal~~ portion of the bushing. See ¶43-45 (exploded-view pictures of Original/Buckle Devices). The proximal end of the capsule receives the ~~reduced diameter distal~~ portion of the bushing and ~~a connection is formed~~ the two components are coupled to one another when the prongs of the spring tab further ~~engage extend through~~ engage extend through holes located near the proximal end of the capsule. This connection between the bushing and capsule is released when, ~~after the control wire is pulled proximally to the [sic] where the Hooks mechanically fail as described above, the control wire is further pulled in the proximal direction such that the hypotube is retracted proximally upon failure of the J-shaped hooks (Original) / C-shaped hooks (Buckle) and engages pushes against~~ the three-pronged spring tab, causing the prongs of the spring to be pulled out of engagement with the holes located at the proximal end of the capsule, freeing the capsule and the clip from the remainder of the device so that the clip remains in the body clipped to the target tissue. See, e.g., MT00000166. In this manner, the bushing is releasably coupled to the capsule “via the a tab (reduced diameter portion) on the distal end of the bushing engaging the opening in the proximal end of the capsule” – i.e., via the distal portion of the bushing and the prongs of the three-pronged spring tab engaging the opening in the proximal end of the capsule.

Compare Ex. A at ¶146 with Ex. D at 5 (same for ¶147 and Lockado). In his Infringement Reply Report, Mr. Leinsing then explicitly labeled the “tab” as “the combination of the distal portion of the bushing and three-pronged spring tab.” See Ex. C at ¶107. Apparently not satisfied with the new arguments in his Reports on this issue, Mr. Leinsing changed course again in his deposition and stated that “[t]he spring tabs are the claimed tabs on the distal end of the bushing.” Ex. F at 155:23-156:3. In addition, in his deposition, Mr. Leinsing specifically rejected the position disclosed in Plaintiffs' Final Infringement Contentions:

Q. So if plaintiffs' infringement contentions said the reduced diameter portion of the bushing was the claimed tab, would you agree or disagree with that position?

A. I would disagree, that it's the -- it's the spring tabs we talked about earlier that are the tabs on the distal end of the bushing.

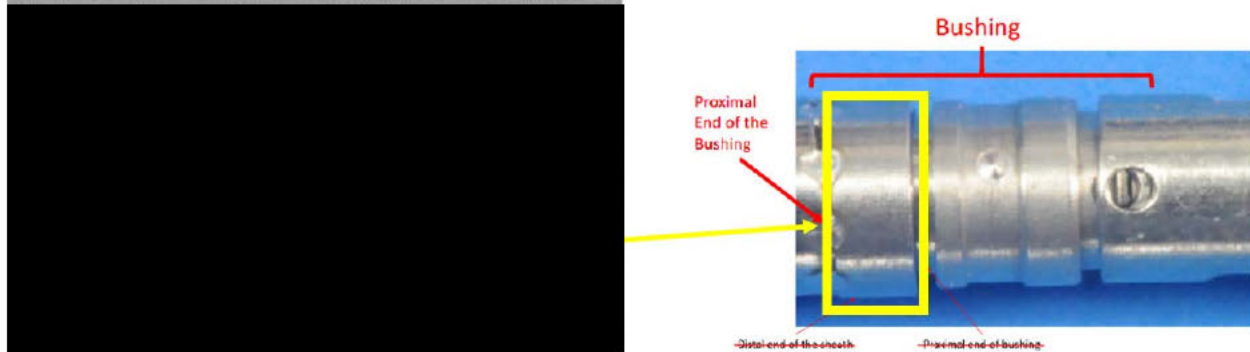
Ex. F at 158:1-7. Mr. Leinsing's new arguments for claim element 1[d] (Ex. A ¶¶142-147) should be struck.

Mr. Leinsing also presented a new doctrine of equivalents argument at Paragraph 148 of his Opening Report for the “tab on the distal end of the bushing” element. Plaintiffs' Infringement Contentions did not present such a DOE argument. This new DOE argument should be struck.

TQ Delta, LLC v. Adtran, Inc., Civil Action No. 15-121-RGA, 2020 WL 4529865, *1–*2 (D. Del. July 31, 2020) (striking DOE theory first disclosed in reply expert report).

b. '371 Claim 1, '725 Claims 2 and 3 – “bushing”

Plaintiffs' Final Infringement Contentions (as well as Mr. Leinsing's Opening Report) identified the bushing as “coupled to the distal end of the coil shaft” and including “clearance between the sheath” to allow the bushing to rotate from the sheath. Ex. E at 5; *accord* Ex. A at ¶145,150. For claims 2 and 3 of the '725 patent, Plaintiffs simply referred back to claim 1 of the '371 patent. In Mr. Leinsing's Reply Report (below image on right), however, the “bushing” *for the first time* was said to include part of the coil shaft:



Ex. C ¶102 (Red in original; yellow added for this letter); *see* BSC-MT-109280 (image on left). Indeed, there is no “clearance” between what Mr. Leinsing now argues to be the bushing and the “coil shaft,” because his “bushing” now includes the coil shaft. This new argument (Ex. C ¶¶100-105) should be struck.

2. New Arguments on the Clip Assembly

Plaintiffs' Final Infringement Contentions and Mr. Leinsing's Opening Expert Report defined the claimed “clip assembly” to constitute the following components in the Accused Products:

Final Infringement Contentions

Leinsing Opening Report

For the Accused Original/Buckle Devices, two clip arms (that together comprise a multi-legged grasping device) are coupled together by a distal pin and a proximal pin, and can be locked in position upon deployment by a tab on the proximal arms and an internal counterbore within the capsule, all of which together form a clip assembly. For the Accused Lockado Devices, two clip arms (that together comprise a multi-legged grasping device) are coupled together by a distal pin, and can be locked in position upon deployment by a tab on the proximal arms and an internal counterbore within the capsule, all of which together form a clip assembly.

140. Each of the Accused Devices includes the claimed clip assembly. For the Accused Original/Buckle Devices, the clip assembly includes the clip (i.e., the two clip arms that comprise a multi-legged grasping device as I describe above in § VII.A.2), the proximal and distal pins, and the internal counterbores of the capsule that lock the clip in a closed configuration after it has been fired (as described above in § VII.C). *See* ¶¶ 43-45 (exploded view pictures of Accused Original/Buckle Devices). For the Accused Lockado Devices, the clip assembly includes the clip (i.e., the two clip arms that comprise a multi-legged grasping device as I describe above in § VII.A.2), the distal pin, and the internal counterbores of the capsule that lock the clip in a closed configuration after it has been fired (as described above in Paragraphs as described above in § VII.C). *See* ¶ 46 (exploded view picture of Accused Lockado Device).

See Exs. A at ¶149, Ex. E at 3-4. Mr. Leinsing's Reply Report attempts to exclude the “internal counterbores” as being part of the clip assembly in a footnote. *See* Ex. C at p. 83-84, fn. 9. This is a new argument raised for the first time in Mr. Leinsing's Reply Report and contradicts his Opening Report and Plaintiffs' Final Infringement Contentions. Thus, Paragraphs 123-126 of Mr. Leinsing's Reply Report should be struck.

3. New Arguments on the Priority Date for the '245 Patent

Mr. Leinsing's Rebuttal Validity Report includes a new alleged priority date for the '245 patent of [REDACTED], a date that Plaintiffs never disclosed in discovery. Ex. B at ¶41, 163-170. In response to Defendants' Interrogatory No. 10 seeking Plaintiffs' position on any conception and reduction to practice, Plaintiffs disclosed two potential priority dates: [REDACTED]

[REDACTED] Ex. G at 2. Later in discovery, however, Plaintiffs' lead counsel expressly represented that Plaintiffs would not assert a priority date before the October 5, 2001 filing date of the '245 Patent. See Ex. H (September 2, 2020 email, highlighted portion). That representation was made as a condition of Defendants withdrawing their demand to depose the named inventor on the '245 patent, Mark Adams. Based on that representation, Defendants did not move forward with the deposition of Mr. Adams, and they also withheld pursuit of other discovery directed to the earliest possible priority date for certain Olympus prior art. Mr. Leinsing first disclosed Plaintiffs' intent to rely on a [REDACTED] priority date in his Rebuttal Report in response to Defendants' position that an Olympus prior art reference had a priority date of October 4, 2001 – a date that Defendants timely disclosed during fact discovery. Mr. Leinsing's untimely reliance on a new [REDACTED] priority date should be struck.

4. New Arguments in the Rebuttal Report on Plaintiffs' Practicing Products

As part of their lost profits claim in this case, Plaintiffs alleged that their Resolution and Resolution 360 clips practice the Asserted Claims. This formed the basis for Dr. Bone's (Plaintiffs' damages expert) lost profits analysis in his Opening Expert Report. Ex. H. But Plaintiffs did not provide any opinion or analysis by Mr. Leinsing, or any other expert, in an opening report. Instead, Plaintiffs waited until Mr. Leinsing's Rebuttal Invalidity Report. Because Plaintiffs bear the burden on lost profits, including by proving that their own products practice the Asserted Claims, the Scheduling Order required any opinions to be expressed in opening expert reports on October 23, 2020. Because it is now too late for defendants to respond to this previously undisclosed opinion of Mr. Leinsing, it should be struck.

5. Claim Elements Newly Disputed in Leinsing Rebuttal Validity Report

With respect to the '725 patent, Plaintiffs did not dispute during discovery that: (a) Sugiyama and Kortenbach I each disclose claim 2; (b) any cited prior art reference discloses claim 3, (c) Kortenbach I discloses claim 6; (d) Kortenbach I and Kimura each disclose claims 8-11, and (e) Kortenbach I discloses claims 1, 12, and all other dependent claims. Nonetheless, the Leinsing Rebuttal Invalidity Report disputes each of those positions. Mr. Leinsing's new opinions on these elements (Ex. B Sections XIV.A.2.b, 4.c,e-h, 8a-i) should be struck as untimely.

Plaintiffs justification for Mr. Leinsing's assertion of new, previously undisclosed validity arguments is that "validity contentions are not required in Delaware and were not contemplated in the Court's scheduling order." See Ex. I. Plaintiffs further allege that, because Interrogatory No. 11 cited to Defendants' Initial Invalidity Contentions, Plaintiffs were not obligated to supplement their discovery responses to address Defendants' Final Invalidity Contentions. *Id.* That position is belied by the fact that Plaintiffs did supplement and respond to Defendants' Final Invalidity Contentions on the last day of fact discovery. Ex. I at 47. Yet, none of the above disputes were included. As a result, the Leinsing Rebuttal Validity Report should not be permitted to assert new anticipation disputes as well as dozens of new obviousness disputes. These arguments should all be struck from Mr. Leinsing's Rebuttal Validity Report.

The Honorable Christopher J. Burke

January 13, 2021

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Respectfully,

/s/ Andrew C. Mayo

Andrew C. Mayo (#5207)

ACM/nlm
Attachment

cc: All Counsel of Record (via electronic mail; w/attachment)